

Water- and wastewater-related disease and infection risks: what is an appropriate value for the maximum tolerable additional burden of disease?

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ABSTRACT

The maximum additional burden of water- and wastewater-related disease of 10^{-6} disability-adjusted life year (DALY) loss per person per year (pppy), used in the WHO Drinking-water Quality Guidelines and the WHO Guidelines for Wastewater Use in Agriculture, is based on US EPA's acceptance of a 70-year lifetime waterborne cancer risk of 10^{-5} per person, equivalent to an annual risk of 1.4×10^{-7} per person which is four orders of magnitude lower than the actual all-cancer incidence in the USA in 2009 of 1.8×10^{-3} pppy. A maximum additional burden of 10^{-4} DALY loss pppy would reduce this risk to a more cost-effective, but still low, risk of 1.4×10^{-5} pppy. It would increase the DALY loss pppy in low- and middle-income countries due to diarrhoeal diseases from the current level of 0.0119 pppy to 0.0120 pppy, and that due to ascariasis from 0.0026 pppy to 0.0027 pppy, but neither increase is of public-health significance. It is therefore recommended that the maximum additional burden of disease from these activities be increased to a DALY loss of 10^{-4} pppy as this provides an adequate margin of public-health safety in relation to waterborne-cancer deaths, diarrhoeal disease and ascariasis in all countries.

Key words | agriculture, ascariasis, burden of disease, diarrhoeal disease, tolerable risks, wastewater use

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INTRODUCTION

The choice of an appropriate value for the maximum tolerable additional burden of disease, expressed as a DALY (disability-adjusted life year) loss per person per year (pppy) due to water-related activities (such as drinking water, using wastewater in agriculture and/or aquaculture, or swimming in recreational waters), is crucial because it sets the resulting tolerable disease and infection risks, as follows:

Tolerable disease risk pppy

$$= \frac{\text{Tolerable DALY loss pppy}}{\text{DALY loss per case of disease}}$$

Tolerable infection risk pppy

$$= \frac{\text{Tolerable disease risk pppy}}{\text{Disease/infection ratio}}$$

It is therefore the primary parameter in quantitative microbial risk analysis (QMRA) which is the currently recommended procedure for determining the required pathogen reductions in wastewater use in agriculture (EPHC/NRMMC/AHMC 2006; WHO 2006). Following the concept of the 'Stockholm Framework', whereby the tolerable health risks resulting from any water-related exposure, be it drinking fully-treated drinking water, working in wastewater-irrigated fields and/or consuming wastewater-irrigated foods, or swimming in recreational waters, should be the same (Fewtrell & Bartram 2001), the value of the maximum tolerable additional burden of disease used for wastewater use in agriculture was taken as 10^{-6} DALY loss pppy (EPHC/NRMMC/AHMC 2006; WHO 2006) as this is the value used to establish the maximum

permissible or recommended concentrations of carcinogens, such as pesticides, in drinking water (NHMRC/NRMMC 2004; WHO 2008).

WHY A MAXIMUM DALY LOSS OF 10^{-6} PER PERSON PER YEAR?

The explanation given in the third edition of the WHO Drinking-water Quality Guidelines (WHO 2008) for a maximum DALY loss of 10^{-6} pppy is as follows (volume 1, section 3.3.2):

“A reference level of risk enables the comparison of water-related diseases with one another and a consistent approach for dealing with each hazard. For the purposes of these Guidelines, a reference level of risk is used for broad equivalence between the levels of protection afforded to toxic chemicals and those afforded to microbial pathogens. For these purposes, only the health effects of waterborne diseases are taken into account. The reference level of risk is 10^{-6} disability-adjusted life-years (DALYs) per person per year, which is approximately equivalent to a lifetime excess cancer risk of 10^{-5} (i.e., 1 excess case of cancer per 100 000 of the population ingesting drinking water containing the substance at the guideline value over a life span).”

This “lifetime excess cancer risk of 10^{-5} ” (more completely, the 70-year lifetime waterborne cancer risk of 10^{-5} per person) was chosen as the basis for the derivation of the 10^{-6} DALY loss pppy because the US Environmental Protection Agency uses a waterborne cancer risk of 10^{-5} – 10^{-6} per person from drinking 2 litres of fully-treated drinking water containing a carcinogen at its maximum contaminant level per day for 70 years (Munro & Travis 1986). WHO (2008) notes that different cancers have different severities, manifested mainly by different mortality rates; using the example of renal cell cancer associated with exposure to bromate in drinking water, this maximum lifetime waterborne cancer risk of 10^{-5} per person was converted to a DALY loss pppy, as follows (volume 1, section 3.3.3):

“The theoretical disease burden of renal cell cancer, taking into account an average case:fatality ratio of 0.6 and

average age at onset of 65 years, is 11.4 DALYs per case. These data can be used to assess tolerable lifetime cancer risk and a tolerable annual loss of DALYs. Here, we account for the lifelong exposure to carcinogens by dividing the tolerable risk over a life span of 70 years and multiplying by the disease burden per case: (10^{-5} cancer cases/70 years of life) \times 11.4 DALYs per case = 1.6×10^{-6} DALY [loss] per person-year.”

The USEPA-accepted maximum 70-year lifetime waterborne cancer risk of 10^{-5} per person can be converted to an annual risk per person, as follows:

$$P_{D(70)} = 1 - [1 - P_{D(1)}]^{70} \quad (1)$$

where $P_{D(70)}$ is the risk of contracting a waterborne cancer per person per 70-year life, and $P_{D(1)}$ is the risk of contracting a waterborne cancer pppy. Thus:

$$P_{D(1)} = 1 - [1 - P_{D(70)}]^{1/70} \quad (2)$$

For $P_{D(70)} = 10^{-5}$, $P_{D(1)} = 1.4 \times 10^{-7}$ – i.e., every resident of the United States has a maximum annual risk of contracting a waterborne cancer of approximately 1 in 10 million.

Whether this is a reasonable level of tolerable risk can only be judged by knowing how many American residents contract cancer each year. Altekruze *et al.* (2010) give the average 1975–2007 age-adjusted incidence of all cancers in both sexes and all races in the United States as 461.76 per 100,000 population – i.e., an incidence of 4.6×10^{-3} pppy. Thus the USEPA-accepted maximum waterborne-cancer risk of 1.4×10^{-7} pppy is over four orders of magnitude lower than the actual all-cancer incidence of 4.6×10^{-3} pppy.

In Australia the situation is even more conservative: the 2004 Australian Drinking Water Guidelines use a 70-year lifetime waterborne cancer risk of 10^{-6} per person, rather than 10^{-5} per person – the reasons for this choice are given as (NHMRC/NRMMC 2004, section 6.4):

“Whether the assumed risk should be one in 100 000 or one in a million is a value judgment. However, the greater degree of protection afforded by a risk of one in a million is generally consistent with calculations based on a threshold approach, and is in line with the high expectations of Australian consumers.”

The annual risk equivalent to 10^{-6} per person per 70-year life is 1.4×10^{-8} per person. There were 100,514 new cases of cancer in Australia in 2005 (AIHW/AACR 2008) when the population of the country was 20,328,600 (ABS 2008), so the all-cancer incidence was 4.9×10^{-3} pppy. Thus the accepted waterborne-cancer risk of 1.4×10^{-8} pppy is over five orders of magnitude lower than the actual all-cancer incidence of 4.9×10^{-3} pppy.

This suggests that 10^{-5} and 10^{-6} waterborne cancer risks per person per 70 – year lifetime are extremely overcautious and unlikely to be cost-effective, and that a maximum DALY loss of 10^{-6} pppy is correspondingly very conservative and cost-ineffective.

HIGHER MAXIMUM DALY LOSSES

The WHO Drinking-water Quality Guidelines (2008) state that higher values for the maximum DALY loss pppy can be used (WHO 2008, volume 1, section 3.3.3):

“Where the overall burden of disease from microbial, chemical or natural radiological exposures by multiple exposure routes (water, food, air, direct personal contact, etc.) is very high, setting a 10^{-6} DALY [loss] per person per year level of disease burden from waterborne exposure alone will have little impact on the overall disease burden. ... Setting a less stringent level of acceptable risk, such as 10^{-5} or 10^{-4} DALY [loss] per person per year, from waterborne exposure may be more realistic, yet still consistent with the goals of providing high-quality, safer water and encouraging incremental improvement of water quality.”

There is a similar statement in WHO Guidelines for Wastewater Use in Agriculture (WHO 2006, section 4.5):

“Wastewater treatment may be considered to be of a low priority if the local incidence of diarrheal disease is high and other water-supply, sanitation and hygiene-promotion interventions are more cost-effective in controlling transmission. In such circumstances, it is recommended that, initially, a national standard is established for a locally appropriate level of tolerable additional burden of disease based on the local incidence of diarrheal disease – for example, $\leq 10^{-5}$ or $\leq 10^{-4}$ DALY [loss] per person per year.”

Therefore the question is whether a maximum DALY loss of 10^{-4} pppy is an appropriate choice.

REASONS IN FAVOUR OF A MAXIMUM DALY LOSS OF 10^{-4} PER PERSON PER YEAR

Cancer

A 10^{-4} DALY loss pppy would be equivalent to a waterborne cancer risk of 1.4×10^{-5} pppy – i.e., 2–3 orders of magnitude lower than the actual fatalallcancer incidences in Australia and the USA. This would appear to provide a reasonable, but less extravagant, margin of safety.

Diarrhoeal disease

The US Environmental Protection Agency accepts a waterborne-disease infection rate of 10^{-4} pppy and, using a disease/infection ratio of 0.1 (as used by US EPA), this is equivalent to a waterborne-disease risk of 10^{-5} pppy (Macler & Regli 1992). Haas (1996) comments on the use of this tolerable waterborne-disease infection risk of 10^{-4} pppy as follows:

“It is becoming apparent that some key factors used for computing the 1:10,000 level of acceptable risk may not be correct. ... The total burden of waterborne illness associated with current water treatment practice in the United States may be as high as several million cases per year. This would translate to an annual illness rate of perhaps 1:100, suggesting that the current benchmark [of 1:10,000] may be far too stringent.”

Haas’ viewpoint is supported by Colford *et al.* (2006) who determined the number of cases of ‘acute gastrointestinal illness’ from community drinking-water systems in the United States, which served 272.2 million people in 2004, to be 4.26–11.69 million cases annually – i.e., an incidence of 1.6×10^{-2} – 4.3×10^{-2} pppy.

Support for Haas’ viewpoint also comes from the current extremely high global incidence of diarrhoeal disease which, in order-of-magnitude terms, is 0.1–1 pppy (Table 1). A tolerable diarrhoeal disease risk of 10^{-2} – 10^{-1} pppy, equivalent to a 10^{-4} DALY loss pppy (Table 2), is an order of magnitude lower than the current global incidence of diarrhoeal disease.

Table 1 | Diarrhoeal disease (DD) incidence per person per year in 2000

World region	DD incidence in all ages	DD incidence in 0–4 year olds	DD incidence in 5–80+ year olds
Industrialized countries	0.2 ^a	0.2–1.7	0.1–0.2
Developing countries	0.8–1.3	2.4–5.2	0.4–0.6
Global average	0.7	3.7	0.4

^aIn some industrialized countries diarrhoeal disease incidence is much higher – for example, 0.8–0.92 pppy for ‘infectious gastroenteritis’ in Australians of all ages (Hellard *et al.* 2001; Hall *et al.* 2005); 0.79 pppy for ‘acute gastroenteritis’ (Mead *et al.* 1999), and 0.72 pppy and 0.6 pppy for ‘acute diarrheal illness’ (Imhoff *et al.* 2004; Jones *et al.* 2007), in Americans of all ages; and in a review paper Roy *et al.* (2006) report all-age incidences of ‘acute gastrointestinal illness’ of 0.3–3.5 pppy in the USA – i.e., mostly in or above the all-age developing-country range shown in the table.

Source: Mathers *et al.* 2002.

For an individual this is equivalent to an additional episode of diarrhoeal disease once every 10 years, which is scarcely a matter of significant public health concern.

Further support for a 10^{-4} DALY loss pppy comes from the fact that in low- and middle-income countries diarrhoeal diseases caused a total DALY loss of 59 million in 2001 (Ezzati *et al.* 2006; Lopez *et al.* 2006). Thus in that year, for the then total developing-country population of 4,940 millions (UNFPA 2002), the DALY loss due to diarrhoeal diseases was:

$$\frac{59 \text{ million DALYs lost per year}}{4,940 \text{ million people}} = 0.0119 \text{ pppy}$$

An additional DALY loss of 10^{-4} pppy would increase this to 0.0120 pppy. Such an increase is not epidemiologically significant and, in any case, would be extremely difficult to detect.

Ascariasis

One of the commonest diseases resulting from the use of wastewater in agriculture is intestinal geohelminthiasis, principally due to *Ascaris lumbricoides* (the human roundworm), *Trichuris trichiura* (the human whipworm) and *Ancylostoma*

duodenale and *Necator americanus* (the human hookworms) (Shuval *et al.* 1986), of which *Ascaris* is generally the most common. de Silva *et al.* (2003) report a DALY loss in low- and middle-income countries due to ascariasis of 10.5 million in 1990 when the population of these countries was 4,053 millions (World Bank 1991). Therefore the DALY loss due to ascariasis was:

$$\frac{10.5 \times 10^6}{4,053 \times 10^6} = 0.0026 \text{ pppy}$$

An additional DALY loss of 10^{-4} pppy would increase this to 0.0027 pppy. Again, such an increase is not epidemiologically significant and would also be very difficult to detect.

LESSONS FROM QUANTITATIVE MICROBIAL RISK ANALYSES

Lesson number 1

Shuval *et al.* (1997) used QMRA to estimate that the risk of hepatitis A from eating 100 g of lettuce irrigated with treated wastewater containing 1000 faecal coliforms per 100 ml (the

Table 2 | DALY losses, tolerable disease risks, disease/infection ratios and tolerable infection risks for norovirus, *Campylobacter*, *Cryptosporidium* and *Ascaris*

Pathogen	DALY loss per case of disease	Tolerable disease risk pppy for 10^{-4} DALY loss pppy	Disease/infection ratio	Tolerable infection risk pppy
Norovirus	9.0×10^{-4}	1.1×10^{-1}	0.8	1.4×10^{-1}
<i>Campylobacter</i>	4.6×10^{-5}	2.2×10^{-2}	0.7	3.1×10^{-2}
<i>Cryptosporidium</i>	1.5×10^{-5}	6.7×10^{-2}	0.3	2.2×10^{-1}
<i>Ascaris</i>	8.3×10^{-5}	1.2×10^{-2}	1 ^a	1.2×10^{-2}

^aTaken as the worst-case scenario.

Sources: Chan 1997; Havelaar & Melse 2003; Kemmeren *et al.* 2006; Moe 2009.

1989 WHO Guideline value (WHO 1989)) on alternate days was $\sim 10^{-7}$ per person per year (pppy). They also determined that the extra expenditure required to treat wastewater from 1000 faecal coliforms per 100 ml to the US EPA/USAID guideline value of “no detectable fecal coli/100 ml” (US EPA & USAID 1992), which would reduce the risk to $\sim 10^{-10}$ pppy, was US\$35 million per case of hepatitis A averted. This is a clearly unjustifiable expenditure – about six cases of hepatitis A so averted would pay for a 300-bed hospital (for example, the 300-bed Sharp Memorial Hospital in San Diego, CA cost around USD 200 million (Garrick 2009)).

Lesson number 2

Tanaka *et al.* (1998) used a dataset of viral concentrations in the effluents of advanced wastewater treatment plants in California, designed to achieve the Californian standard of ≤ 2.2 total coliforms per 100 ml for unrestricted irrigation (CDPH 2009), to show by QMRA that the infection risks to consumers of wastewater-irrigated salad crops irrigated with ‘fully’ treated wastewater (‘fully’ means a 5.2-log unit virus reduction after primary, secondary and tertiary treatment and chlorination) were in the range 10^{-8} – 10^{-10} pppy – i.e., at least *four* orders of magnitude lower than the value of 10^{-4} pppy accepted by US EPA as the tolerable waterborne-disease infection risk from drinking fully-treated drinking water (Macler & Regli 1992).

These two lessons raise two important questions:

(1) whether the risks from consuming wastewater-irrigated foods should be so much lower than those from drinking fully-treated drinking water, and (2) whether very large expenditures on wastewater treatment to achieve such very low risks are justified. If the answer to the first question is ‘No’, and there does not appear to be any valid reason why the answer should not be ‘No’, then it follows that the answer to the second question is also ‘No’. This demonstrates the need to base decisions on *actual* risks to health, rather than on merely *potential* risks, as recommended by WHO (1989).

DISCUSSION

QMRA models the risks to exposed individuals resulting from exposure to a single pathogen, whereas exposed individuals

are exposed to all pathogens present in the exposure medium. This limitation can be at least partially overcome by conducting QMRA-Monte Carlo risk simulations for all pathogens present, or likely to be present, in a particular exposure medium for which there are dose-response data – for example, Mara *et al.* (2007) performed risk simulations for rotavirus, *Campylobacter* and *Cryptosporidium* for both restricted and unrestricted irrigation and found that the QMRA-Monte Carlo simulated risks for *Campylobacter* and *Cryptosporidium* were always lower than those for rotavirus; and Mara *et al.* (2010) and Scheierling *et al.* (2010) found that the simulated risks for norovirus and rotavirus in unrestricted irrigation were broadly similar, whereas those for *Ascaris* were not. This suggests that, for wastewater use in agriculture, routine QMRA-Monte Carlo risks simulations for norovirus and *Ascaris* would be sufficient, although of course this should be checked for every set of exposure conditions.

The calculations given herein may seem to represent a somewhat ‘cold’ and/or ‘mechanical’ approach to the evaluation of tolerable risk, especially as society perceives risk in an essentially more emotional way. For example, most individuals expect the water they drink and the food they eat to be ‘perfectly safe’ – that is to say, they expect that there should be, or unthinkingly assume that there is, no risk associated with the water and food they consume, whereas of course there is no such thing as a zero risk (the risk may be extremely small, but it is not zero). Moreover they do not normally make any comparison between risks due to different causes. Thus, whereas society may reluctantly accept that fatal road traffic accidents (RTA) and homicides do from time to time occur, it might be more reluctant to accept that cancer could occur as a result of drinking fully-treated drinking water. Yet the risks involved, when expressed numerically, do not support such a position – for example, as shown in Table 3, the global risks of homicide and dying from an RTA are 7.7×10^{-5} pppy and 1.9×10^{-4} pppy, respectively, and for the USA these risks are 6.1×10^{-5} pppy and 1.9×10^{-4} pppy – i.e., *two* and *three* orders of magnitude greater than the US EPA-accepted maximum risk of a waterborne cancer of 1.4×10^{-7} pppy. This indicates that society should be 100–1000-times more worried about dying from these causes than it is about waterborne cancers. That this is not the case suggests that society needs to be better educated about the risks it runs, rather than being content to rely on ill-founded

Table 3 | Risks of dying from homicide and a road traffic accident in the world and the USA

Cause of death	Location (year)	Number of deaths	Population	Risk of dying from cause of death (pppy)	References
Homicide	World (2004)	490,000	6,377,600,000	7.7×10^{-5}	UNOCD (2009); UNFPA 2005
	USA (2007)	–	–	6.1×10^{-5}	Xu <i>et al.</i> 2010
Road traffic accident	World (2002)	1,183,492	6,211,100,000	1.9×10^{-4}	Peden <i>et al.</i> 2004; UNFPA 2003
	USA (2002)	56,199	288,500,000	1.9×10^{-4}	Peden <i>et al.</i> 2004; UNFPA 2003

perceptions of risk or on less-than-perfect guidance on risk acceptability from governmental agencies. This is pertinent in all countries, but especially so in low-income countries which can ill afford to provide high levels of protection against low-risk events like waterborne cancers.

Policy makers in all countries need to be able and willing to justify in detail the decisions they make on levels of tolerable risk and to understand the cost implications and the cost-effectiveness of their decisions. Given that such decisions are political decisions, politicians need good justifiable advice from civil servants and/or government agencies, although legislative responsibility may be delegated by legislators to regulatory agencies. Whether or not the recommendations made herein will be accepted by politicians/regulators will depend on several factors, including whether they accept the arguments made and, even if they do, whether they feel able to do so publically, especially if this means a revocation of their earlier position. A recent review of the regulatory excesses of the US EPA (Miller 2009) suggests that such acceptance may be not be readily forthcoming.

Nevertheless it is important that ‘risk-literate’ professionals always seek to question politicians/regulators closely about their legally enforced levels of tolerable risk for the reasons given by Miller and Conko (2001):

“Money spent on implementing and complying with regulation (justified or not) exerts an “income effect” that reflects the correlation between wealth and health, an issue popularized by the late political scientist Aaron Wildavsky. It is no coincidence, he argued, that richer societies have lower mortality rates than poorer ones. To deprive communities of wealth, therefore, is to enhance their risks. Wildavsky’s argument is correct: Wealthier individuals are able to purchase better health care, enjoy

more nutritious diets, and lead generally less stressful lives. Conversely, the deprivation of income itself has adverse health effects – for example, an increased incidence of stress-related problems including ulcers, hypertension, heart attacks, depression, and suicides. It is difficult to quantify precisely the relationship between mortality and the deprivation of income, but academic studies suggest, as a conservative estimate, that every \$7.25 million of regulatory costs will induce one additional fatality through this ‘income effect’. The excess costs in the tens of billions of dollars required annually by precautionary regulation for various classes of consumer products would, therefore, be expected to cause thousands of deaths per year. These are the real costs of ‘erring on the side of safety’. The expression ‘regulatory overkill’ is not merely a figure of speech.”

Arguably any extravagant excesses of regulators are only likely to be constrained by organizations such as the Government Accountability Office in the United States, the National Audit Office in the United Kingdom, and the Court of Auditors in the European Union, so risk professionals should also address their concerns to these agencies.

CONCLUSIONS

1. A maximum additional burden of disease from water- and wastewater-related activities of 10^{-6} DALY loss pppy cannot be considered realistic or cost-effective, even in high-income countries.
2. It is therefore recommended that the maximum additional burden of disease from these activities be increased to a DALY loss of 10^{-4} pppy. This is likely to be much more cost-effective, yet still provide adequate margins of

public-health safety in relation to waterborne cancer, diarrhoeal disease and ascariasis in all countries.

- Legislators/regulators should always be asked to justify the decisions they make on levels of tolerable risk and to detail the cost implications and cost-effectiveness of these decisions.

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